

**Notice of Allowability**

Application No.

10/065,547

Examiner

Robert B. Davis

Applicant(s)

LAGHI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the telephone interview of 02 February 2005.
2. ☒ The allowed claim(s) is/are 1-17.
3. ☒ The drawings filed on 29 October 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 2/2/05.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ronald E. Smith on February 2, 2005.

The application has been amended as follows:

The title has been amended as follows:

Apparatus and ~~Method~~ for Casting a Prosthetic Socket Under Vacuum

In the specification:

Paragraph 24 has been amended as follows:

(0024) In a first embodiment, a prosthetic liner is positioned in overlying relation to a residual limb and a first plastic separator is placed into overlying relation to the liner. Plaster bandage means that have been soaked in water are wrapped around the first plastic separator. A second plastic separator is applied in overlying relation to the plaster bandage means and a vacuum wick means is positioned in overlying relation to the second plastic separator. The residual limb, liner, first plastic separator, plaster bandage means, second plastic separator, and said vacuum wick are inserted into a vacuum bladder. A hemostatic latch is then sealed over a proximal end of the vacuum bladder and a predetermined vacuum is applied internally to the vacuum bladder for a predetermined amount of time until the plaster means hardens into a negative cast.

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The residual limb is manipulated through the vacuum bladder before the plaster means hardens to modify the geometry of the plaster means as appropriate for the physiology of the residual limb. The negative cast is removed from the residual limb and a positive cast is produced by pouring plaster into the negative cast. A finished prosthetic socket is then made by thermoforming a thermoplastic sheet over the positive cast or by laminating a carbon-epoxy matrix over said positive cast.

The claims have been amended. A copy of the amended claims is attached to this document.

#### Claim Interpretation

2. The phrase "tubing means" is being interpreted as "tubing" and not as a means plus function limitation. The phrase "wick means" is being interpreted as "wick" and not as a means plus function limitation. The phrase "unhardened plaster means" is being interpreted as unhardened plaster and the equivalent listed in paragraph 11 of the specification and not as a means plus function limitation.

3. The following is an examiner's statement of reasons for allowance: None of the prior art of record teaches or suggests the combination of elements of claims 1 or 9, specifically the combination of a vacuum source, a vacuum bladder having a closed distal end and an open proximal end, tubing between the vacuum source and the distal end of the bladder, a first plastic separator or a liner, a layer of unhardened plaster, a wick and a hemostatic latch for forming a prosthetic socket. The closest prior art (Laghi 5,503,543) discloses applying manual pressure to plaster wrapped around a residual limb as background of the invention and then a cylinder, pressure source and bladder

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used to apply reliable pressure to the plaster; however, the reference does not disclose or suggest the use of a vacuum bladder connected to a vacuum source for applying vacuum to the area between the bladder and the residual limb. It is not an obvious substitution as the use of the vacuum bladder allows for fluid pressure and manual pressure to be applied simultaneously to modify the plaster as it hardens in relation to sensitive areas of the residual limb. Caspers (5,376,132) discusses the sensitive areas (column 6, lines 26-44), but uses reduction of a model to form a satisfactory prosthetic. Brown (3,995,002) discloses a bag and vacuum source for forming an impression of a foot, but there is no motivation to one of ordinary skill in the art in any of the cited references to modify any of the residual limb prosthetic devices to use such a bag.

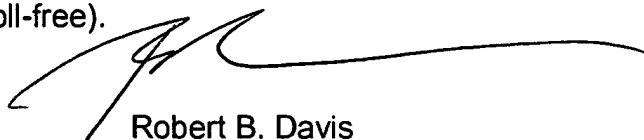
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Davis whose telephone number is 571-272-1129. The examiner can normally be reached on Monday-Friday 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Benjamin L. Utech can be reached on 571-272-1137. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert B. Davis  
Primary Examiner  
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2/2/05~

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Claims listing:

1. (currently amended) An apparatus for making a prosthetic socket, comprising:

- a vacuum source;
- a vacuum bladder having a closed distal end and an open proximal end;
- a tubing means for providing fluid communication between said vacuum source and said distal end of said vacuum bladder;
- said vacuum bladder adapted to receive a residual limb;
- a first plastic separator disposed in overlying relation to said residual limb;
- a layer of unhardened plaster means disposed in overlying relation to said first plastic separator;
- a wick means disposed in overlying relation to said layer of unhardened plaster means;
- a hemostatic latch for sealing said proximal end of said vacuum bladder when said residual limb, first plastic separator, plaster means, and wick means are positioned within said vacuum bladder;
- whereby a predetermined vacuum is capable of being applied internally to said vacuum bladder for a ~~predetermined~~ an amount of time until said plaster means hardens into a negative cast;
- whereby the residual limb is capable of being manipulated through said vacuum bladder before said plaster means hardens to modify the geometry of the plaster means as appropriate for the physiology of the residual limb; and

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whereby the negative cast is capable of being removed from the residual limb and a positive cast is produced by pouring plaster into the negative cast is capable of having a positive cast formed therein.

2. (currently amended) The apparatus of claim 1, further comprising;  
a thermoplastic sheet that is capable of being thermoformed over the positive cast;  
whereby a prosthetic socket is capable of being made in the absence of reduction and modification of a hard positive cast.

3. (currently amended) The apparatus of claim 1, further comprising;  
a carbon-epoxy matrix that is capable of being laminated over the positive cast;  
whereby a prosthetic socket is capable of being made in the absence of reduction and modification of a hard positive cast.

4. (original) The apparatus of claim 1, further comprising a second plastic separator disposed in overlying relation to said unhardened layer of plaster means.

5. (original) The apparatus of claim 1, further comprising a vacuum regulator disposed between said vacuum source and said vacuum bladder.

6. (original) The apparatus of claim 5, further comprising a valve means disposed between said vacuum regulator and said vacuum bladder.

7. (original) The apparatus of claim 5, further comprising a manifold disposed between said vacuum regulator and said vacuum bladder.

8. (original) The apparatus of claim 7, further comprising a vacuum gauge in fluid communication with said manifold, said vacuum gauge adapted to provide a visual display of pressure within said manifold.

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9. (currently amended) An apparatus for making a prosthetic socket, comprising;

a vacuum source;

a vacuum bladder having a closed distal end and an open proximal end;

a tubing means for providing fluid communication between said vacuum source and said distal end of said vacuum bladder;

said vacuum bladder adapted to receive a residual limb;

a prosthetic liner disposed in overlying relation to said residual limb;

a layer of unhardened plaster means disposed in overlying relation to said prosthetic liner;

a wick means disposed in overlying relation to said layer of unhardened plaster means;

a hemostatic latch for sealing said proximal end of said vacuum bladder when said residual limb, prosthetic liner, plaster means, and wick means are positioned within said bladder;

whereby a ~~predetermined~~ vacuum is capable of being applied internally to said vacuum bladder for a ~~predetermined~~ an amount of time until said plaster means hardens into a negative cast;

whereby the residual limb is capable of being manipulated through said vacuum bladder before said plaster means hardens to modify the geometry of the plaster means as appropriate for the physiology of the residual limb; and



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whereby the negative cast is capable of being removed from the residual limb and a positive cast is produced by pouring plaster into the negative cast is capable of having a positive cast formed therein.

10. (currently amended) The apparatus of claim 9, further comprising;  
a thermoplastic sheet that is capable of being thermoformed over the positive cast;  
whereby a prosthetic socket is capable of being made in the absence of reduction and modification of a hard positive cast.

11. (currently amended) The apparatus of claim 9, further comprising;  
a carbon-epoxy matrix that is capable of being laminated over the positive cast;  
whereby a prosthetic socket is capable of being made in the absence of reduction and modification of a hard positive cast.

12. (original) The apparatus of claim 9, further comprising a first plastic separator disposed in overlying relation to said prosthetic liner.

13. (original) The apparatus of claim 12, further comprising a second plastic separator disposed in overlying relation to said unhardened layer of plaster means.

14. (original) The apparatus of claim 9, further comprising a vacuum regulator disposed between said vacuum source and said vacuum bladder.

15. (original) The apparatus of claim 14, further comprising a valve means disposed between said vacuum regulator and said vacuum bladder.

16. (original) The apparatus of claim 14, further comprising a manifold disposed between said vacuum regulator and said vacuum bladder.

17. (original) The apparatus of claim 16, further comprising a vacuum gauge in fluid

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communication with said manifold, said vacuum gauge adapted to provide a visual display of pressure within said manifold.

18-26. (canceled)